PATENT SPECIFICATION

(11) 1 472 312

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(21) Application No. 53122/76 (22) Filed 11 April 1974
(62) Divided out of No. 1472311
(31) Convention Application No. 2318459
(32) Filed 12 April 1973 in
(33) Federal Republic of Germany (DT)
(44) Complete Specification published 4 May 1977
(51) INT CL² A61F 1/24
(52) Index at acceptance
A5R X6

(19)

(54) IMPROVEMENTS RELATING TO ARTIFICIAL JOINTS

(71) We, FELDMÜHLE ANLAGEN-UND PRODUKTIONSGESELL-SCHAFT MIT BESCHRÄNKTER HAFTUNG, a Body Corporate organised according to the laws of the Federal Republic of Germany, of 4 Düsseldorf-Oberkassel, Fritz-Vomfelde-Platz 4, Federal Republic of Germany, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a ball member for an implantable hip-joint prosthesis, and to a hip-joint prosthesis which consists of the ball member and a co-operating socket member.

In prostheses designed to replace sockets and bone parts in contact therewith, for example, the upper femur the firm seating of the co-operating parts in the bone is an important pre-requisite for operability.

In one previous proposal, the joint head (ball member) engaged with the artificial socket is attached to the projecting end of a shaft which has been driven into the medulla area of the upper femur, the joint head being swivel-mounted in the socket. The joint head is anchored to the bone by the shaft embedded therein and it is therefore vital that the joint between the bone and the shaft is sufficiently strong to withstand all the stresses involved.

Materials previously proposed for the shaft have mainly been metals, predominantly corrosion-resistant alloys based on nickel, chromium, cobalt, and molybdenum. According to German Offenlegungschrift No. 2,134,316, a metal shaft is driven into the bone and secured by means of a cement consisting of a high molecular weight acrylic resin (bone cement). It has not proved possible to guarantee that the joint thus produced will be permanently secure. Although the mentioned alloys have a high resistance to corrosion, they have the disadvantage that they cannot be directly anchored in the bone but need cement for this purpose.

As a result of the evolution of heat by the cement as it cures, the temperature can reach up to 120°C, leading to an albumin denaturation in the adjacent tissue, and tissue damage by the cement monomer may also occur. In addition, the metal of the implant may be eroded by electrolytic reaction, leading to the production of metallic particles. If the above reactions do occur then the implant becomes loose.

Another disadvantage of metal implants is their comparatively high specific weight. Furthermore, it is necessary to find a special cement which will satisfactorily bond the very different materials of bone substance and metal.

Considerable difficulties are also caused both for the operating surgeon and the patient. For the introduction of the shaft into the medulla zone, a relatively large proportion of the femur, namely, the femur head and femur neck, must be removed so that very little bone substance remains for possible subsequent operations. Also disadvantageous is the relatively large area of contact between the shaft of the prosthesis and the bone. A relative large contact area always means a relatively large wound area and the increased danger of infection associated therewith. In addition, a relatively large area of the bone tissue is open to attack. A foreign body such as a joint prosthesis frequency brings on a retreat of the natural bone tissue which can extend to a retrogressive metamorphosis. Such decomposition of the bone tissue always results in the prosthesis becoming loose and in renewed problems for the patient.

There is a need for a prosthesis which is light, has high mechanical strength, is capable of withstanding the dynamic stresses to which it is likely to be subjected, has a high abrasion resistance, is as compatible as possible with body tissue,

and has as small as possible an area of contact with the bone.

The present invention provides a ball member for a ball-and-socket hip-joint prosthesis, which ball member has a generally part-spherical front surface for complementary sliding and rotating engagement with a socket, and a rear surface having a polyhedral recess so shaped, to fit over the head of a patient's femur that has been complementarily shaped into a polyhedron, that when in the body of the patient the ball member will remain attached to the head of the femur solely by virtue of the shape of the said polyhedral recess in its rear surface, at least the superficial parts of the ball member consisting of sintered aluminium oxide having a purity greater than 99%, a density greater than 3.9 g/cm^3 and a mean grain size below 10 μm.

The invention also provides a hip-joint prosthesis consisting of a ball member as defined above and a socket member having a generally concave-hemispherical front surface and a rear surface for attachment to the patient's ilium, at least the superficial parts of the socket member consisting of sintered aluminium oxide having a purity greater than 99%, a density greater than 3.9 g/cm^3 and a mean grain size below 10 μm.

The aluminium oxide of both the ball member and the socket member has preferably been sintered at a temperature above 1700°C.

The recessed rear surface of the ball member may have small protuberances but is free of large projections, for example, a shaft.

The ball member will be hereinafter referred to as the joint head.

It is possible that the reason for the suitability of sintered aluminium oxide with a degree of purity of more than 99%, a density of over 3.9 g/cm^3 and a mean grain size of below 10 μm may lie in the fact that, with such a high density as a result of the strong grain binding, there is also a high material strength.

High density sintered aluminium oxide of the kind defined above can be highly polished. Preferably, the parts of the joint in contact with each other, namely the outer part-spherical surface of the joint head and the concave inner surface of the socket, are highly polished so that friction is as low as possible. Advantageously the joint head and socket are fitted one into the other by lapping directly after manufacture. Polished, high density sintered aluminium oxide is not very abrasive, as a result of which there is very little wear of the rubbing surfaces.

After polishing, the inner surface of the socket and the outer surface of the joint head preferably have a mean peak-to-valley height R_a of less than 0.5 μm and preferably at most 0.1 μm. Only extremely pure aluminium oxide, that is to say, containing more than 99% by weight of Al_2O_3, can be polished to this extent.

Of the various measures of mechanical strength, bonding strength is of particular importance for the prosthesis of the invention. As a result of the density lying above 3.9 g/cm^3 and the grain size below 10 μm, the prosthesis has a bending strength greater than 40 kp/mm^2.

The use of alumina having the properties given above represents a complete departure from the previously held expert opinion that ceramic material for use in prostheses has necessarily to be porous to enable the tissue to grow into it; the alumina used according to the invention is a high-density material which is not necessarily porous and, furthermore, may be polished, and so, according to expert opinion, cannot provide a joint with the bone since there are no adjacent rough surfaces. Considerations underlying the present invention lead to the view, however, that, contrary to the former expert opinion, the high-density, sintered aluminium oxide ceramic material defined above is useful in order to obtain not only a high bending strength but also to prevent the grain from breaking away, which was a probable cause of the failure of implants made of porous ceramic.

The high purity of the aluminium oxide not only has a very positive effect on the polishing capability, the mechanical strength and the resistance to abrasion, but simultaneously reduces the risk of contamination from foreign substances, especially silicon oxide and alkaline oxides which may cause considerable foreign body-reactions, in patients. These reactions are started not so much by the implant as such but by the abrasion of the implanted joints which can never be excluded when there is movement, because the abrasion causes a considerably larger surface to be presented for attack by body fluids than would otherwise be the case. Because of the high degree of purity of the aluminium oxide used, the latter is practically free of foreign substances so that any abrasion which does occur is substantially physiologically harmless and therefore does not result in foreign-body reactions in the patient.

It may be advantageous to increase the bending strength, shearing strength and fatigue strength under repeated constantly reversed bending stresses of the parts of the prosthesis of the invention by the use of internal reinforcing inserts, for example, grids, lattices, or fibres. Advantageously,

the materials chosen for these inserts are those which can be strongly bonded by sintering to the aluminium oxide ceramic, metals being preferred.

The joint between the surface of the parts engaging with the bone and the bone itself should, of course, be as strong as possible and this may be assisted by the use of additional mechanical gripping means on the surface in the form of irregularities or roughness on the bone-engaging surfaces. These may be, for example, in the form of barbs, or may simply consist of small projections or a milled surface.

If the bone-engaging surfaces of the prosthesis are irregular or rough, the strength of the bond between prosthesis and bone can be improved to a considerable extent by the bone tissue growing into any depressions present. This is because the kindred materials, bone and aluminium oxide ceramic, gradually grow together, particularly when there are additional mechanical holding means on the contact surface. Furthermore, there is such a high muscle and sinew tension that the joint head is drawn firmly into the joint socket. The prosthesis of the invention thus has the advantage that no cement is necessary, thus reducing expense and avoiding the previously mentioned damaging influences of bone cement on the surrounding tissue.

By the use of the prosthesis of the present invention, attachment by means of a shaft is avoided, but the prosthesis is nevertheless firmly held. In prosthesis where a shaft is employed, this shaft is subjected to bending stresses, whereas the joint head of the prosthesis of the invention is subjected only to compression stresses.

The prosthesis of the invention has the advantage that the two parts thereof are of relatively simple shape, thus simplifying and reducing the costs of their manufacture. In the production of shaped articles of sintered alumina, an uncomplicated shape is a great advantage because of the shrinkage that occurs during sintering.

The arrangement of the invention, in which the joint head is fitted directly over the head of the femur, after suitable machining of the bone, means that there is still sufficient bone substance present for possible subsequent operations. At the same time, the area of contact between the joint head and the bone substance is much less than with a shaft arrangement. Thus the wound area is substantially reduced and retrogressive metamorphosis is less likely to occur. In addition, the area of the bone above the bone marrow is much smaller than with the shaft arrangement, which is an advantage since bone above the marrow is subject to deterioration.

The sintered alumina prosthesis of the invention has, in addition, a higher resistance to corrosion than, for example, the alloys mentioned previously, so that undesired side effects are minimised. As a result of its affinity to the bone substance, apart from the improved bond, the sintered alumina prosthesis has better tissue compatability than have metallic prostheses.

As previously mentioned, the prosthesis of the invention has the advantage that it can be attached directly to the bone without the use of cement. A further advantage lies in the fact that the hammering required to insert previously proposed prostheses and the jolting stress association therewith are avoided completely.

The polyhedral shape of the recess in the joint head and the complementary polyhedral shape of the machined femur head provide a safeguard against twisting. In addition there is the advantage that in the case of local retrogressive metamorphosis of bone tissue there is always a flat contact surface between the joint head and the head of the bone, and thus stabilization of the position of the joint head.

For the same reasons, a part of the outer surface of the joint socket may comprise two generally planar regions inclined to one another at an angle between 0° and 180°. An additional safeguard against twisting may be provided by a tongue-like projection extending from one side of the outer surface of the joint socket, to accommodate fixing means, for example, a screw. This enables a fixing screw to be inserted into a relatively thick region of the pelvic bone.

It may be advantageous if the joint socket is fixed in the pelvic bone by further additional fixing means, for example, countersunk screws. This assists to quite a considerable extent in the stabilisation of the socket.

A prosthesis according to the invention will now be described in further detail, by way of example only, with reference to the accompanying drawing, in which:—

Figure 1 shows a hip-joint prosthesis according to the invention; and

Figure 2 is a view of the socket of the prosthesis of Figure 1 from the direction X shown in Figure 1.

Referring now to Figures 1 and 2 of the accompanying drawings, a hip-joint prosthesis consists of a joint head 10 having a convex generally part-spherical front (outer) surface and a joint socket 14 having a generally concave-hemispherical front

(inner) surface for complementary engagement with the joint head 10.

The rear surface of the joint head 10 has a polyhedral recess inside which the complementarily shaped head 18 of the femur 1 fits. The machined femur head 18 is in contact with the rear surface of the joint head 10 over a planar contact surface 20. The rear surface of the joint socket 14 has two planar surfaces 22 inclined to one another at angle between 0° and 180° to assist in positive bonding with the pelvic bone 13. A tongue 21 projects from one side of the rear surface of the socket 14. The socket 14 is securely joined via the tongue 21 with the pelvic bone 13 by means of a countersunk screw 15.

All parts of the prosthesis shown in the drawings consists of sintered aluminium oxide having a purity greater than 99%, a density greater than 3.9 g/cm³ and a mean grain size below 10 μm. The concave surface of the socket 14 and the convex surface of the joint head 10 are milled and polished.

WHAT WE CLAIM IS:—

1. A ball member for a ball-and-socket hip-joint prosthesis, which ball member has a generally part-spherical front surface for complementary sliding and rotating engagement with a socket, and a rear surface having a polyhedral recess so shaped, to fit over the head of a patient's femur that has been complementarily shaped into a polyhedron, that when in the body of the patient the ball member will remain attached to the head of the femur solely by virtue of the shape of the said polyhedral recess in its rear surface, at least the superficial parts of the ball member consisting of sintered aluminium oxide having a purity greater than 99%, a density greater than 3.9 g/cm³ and a mean grain size below 10 μm.

2. A ball member as claimed in Claim 1, wherein the aluminium oxide has been sintered at a temperature above 1700°C.

3. A ball member as claimed in Claim 1 or Claim 2, which is internally reinforced by metal.

4. A ball member as claimed in any one of Claims 1 to 3, whereof the rear surface is irregular and/or rough.

5. A ball member for a ball-and-socket hip-joint prosthesis, substantially as hereinbefore described with reference to, and as shown in Figures 1 and 2 of the accompanying drawings.

6. A hip-joint prosthesis which comprises a ball member as claimed in any one of Claims 1 to 5, and a socket member having a generally concave-hemispherical front surface and a rear surface for attachment to the patient's ilium, at least the superficial parts of the socket member consisting of sintered aluminium oxide having a purity greater than 99%, a density greater than 3.9 g/cm³ and a mean grain size below 10 μm.

7. A prosthesis as claimed in Claim 6, wherein the aluminium oxide of the socket member has been sintered at a temperature above 1700°C.

8. A prosthesis as claimed in Claim 6 or Claim 7, wherein the socket member is internally reinforced by metal.

9. A prosthesis as claimed in any one of Claims 6 to 8, wherein the rear surface of the socket member is irregular or rough.

10. A prosthesis as claimed in any one of Claims 6 to 9, wherein the rear surface of the socket member has a tongue-like projection for accommodating fixing means.

11. A prosthesis as claimed in any one of Claims 6 to 10, wherein a part of the rear surface of the socket member comprises two planar surfaces inclined to one another at an angle between 0° and 180°.

12. A ball-and-socket joint prosthesis substantially as hereinbefore described with reference to, and as shown in, Figures 1 and 2 of the accompanying drawings.

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Printed for Her Majesty's Stationery Office, by the Courier Press, Leamington Spa, 1977
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

1472312 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

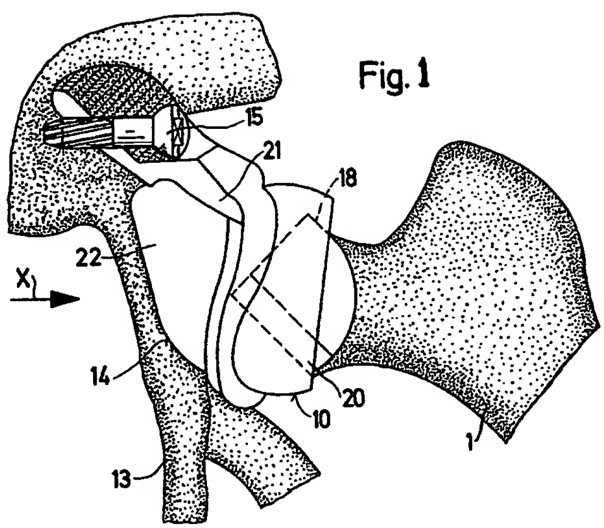

Fig. 1

Fig. 2